भारतीय मानक

IS 18266 : 2023

Indian Standard

वस्त्रादि — चिकित्सा श्वास यंत्र — विशिष्टि

Textiles — Medical Respirator — Specification

ICS 11.140; 59.080.01

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Technical Textiles for Medtech Applications Sectional Committee, TXD 36

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Technical Textiles for Medtech Applications Sectional Committee had been approved by the Textiles Division Council.

Workers, primarily those in the health care profession, involved in treating and caring for individuals injured or sick, can be exposed to biological liquids capable of transmitting disease. These diseases, which may be caused by a variety of microorganisms, can pose significant risks to life and health.

A medical respirator is a respiratory protective device designed to achieve a very close facial fit and covers at least the nose, mouth and may cover the chin. A respirator is worn by healthcare personnel (HCP) to reduce the wearer's risk of inhaling hazardous airborne particles such as dusts, fumes, vapors, infectious agents and aerosol/fluids (for example splashes, sprays) for use in healthcare settings.

This standard does not cover the requirement of surgical face mask which has been covered in 'IS 16289 : 2014 Medical textiles — Surgical face mask — Specification' and for respiratory filtering half masks which has been covered in IS 9473 : 2002 Respiratory protective devices — Filtering half masks to protect against particles — Specification (*first revision*).

The composition of the committee responsible for the formulation of this standard is listed in Annex D.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*second revision*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

TEXTILES — MEDICAL RESPIRATOR — SPECIFICATION

1 SCOPE

1.1 This standard specifies the performance requirements and test methods of medical respirator intended to be worn by operating room personnel/staff during surgical procedures and other healthcare services such as patient care, with similar requirements. Medical respirators are used to protect both the surgical patient and the operating room personnel/staff from transfer of microorganisms, body fluids and particulate material.

1.2 Medical respirator shall not have any exhalation valve. Respirators with exhalation valves are not meant to be used for medical use. Medical respirator is not recommended for washing or reuse due to performance drop (due to washing) and cross contamination (reuse).

1.3 This standard does not address the design, construction, interfaces or other factors which may affect the overall protection offered by the medical respirator.

2 REFERENCES

The standards listed in Annex A contain provisions, which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards listed in Annex A.

3 TERMS AND DEFINITIONS

For the purpose of this standard, the definitions given in IS 8347 and the following shall apply.

3.1 Aerosol — It is the suspension of solid, liquid, or solid and liquid, particles in gaseous medium, the particles having a negligible falling velocity, generally considered to be less than 0.25 m/s.

3.2 Biocompatibility — The ability to be in contact with a living system without producing an adverse effect.

3.3 Breathing Resistance — It is the pressure differential between the upstream and downstream location caused by a medical respirator to the flow of breathable gas during inhalation (inhalation resistance) or exhalation (exhalation resistance).

3.4 Colony Forming Unit (CFU) — A particle containing one or more bacterial cells which gives rise to a single bacterial colony on a culture plate.

3.5 Fluid/Splash Resistance — It is defined as the ability of a respirator's material construction to minimize fluids from travelling through the material and potentially coming into contact with the user of the respirator. Fluid resistance helps reduce potential exposure to blood and body fluids caused from splashes, spray or splatter. Resistance to penetration by synthetic blood is indicated as pass/fail at one of two distinct velocities of 120 mm and 160 mm of Hg. Penetration (visual evidence of synthetic blood on the side opposite impact results in fail at that pressure. Non-penetration results in a pass.

3.6 Healthcare Personnel (HCP) — Refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (for example blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP may include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, students and trainees, contractual staff not employed by the health care facility, and persons (for example clerical, dietary, environmental services, laundry, security, maintenance, engineering and facilities management, administrative, billing, and volunteer personnel) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted among from HCP and patients.

3.7 Infective Agent — The microorganism that has been shown to cause surgical medical wound infection or that might cause infection in the patient or in members of the surgical medical team.

3.8 Manufacturer — Natural or legal person with responsibility for the processing of raw material or inputs in any manner that results in the emergence of a new product having a distinct name, character and use.

3.9 Medical Respirator — A medical respirator is a respiratory protective device designed to achieve a very close facial fit and covers at least the nose, mouth and may cover the chin. A respirator is worn by healthcare personnel (HCP) to reduce the wearer’s risk of inhaling hazardous airborne particles such as dusts, fumes, vapors, infectious agents and aerosol/fluids (for example splashes, sprays) for use in healthcare settings.

NOTE — The edges of the respirator are designed to form a seal around the nose and mouth and may cover the chin.

3.10 Penetration of Filter — Penetration is defined as ratio of sodium chloride (NaCl) concentration (after filter) by sodium chloride concentration (before filter) expressed in percent.

3.11 Surgical Procedure — A surgical intervention penetration skin or mucosa, performed by a surgical team under controlled environmental conditions.

4 MANUFACTURE AND WORKMANSHIP

4.1 The medical respirator shall be made from suitable textiles material that is not prohibited for use for the purpose under any applicable law/regulation in force so that the product made out of this meets the requirements specified in this standard. The fabric used for the manufacturing of medical respirator shall be a single or multi-layered textile structure made of woven or non-woven (spunlace or spunbond or combination of spunbond and meltblown) or knitted structure.

4.2 The medical respirator shall not disintegrate, split or tear during intended use. The medical respirator shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the respirator fits closely at the sides (*see* IS 9623). The manufacturer shall provide the information and instruction for safe use of the product to the user.

4.3 The head harness shall be so designed that the medical respirator can be donned and removed easily. The head harness shall be adjustable/self-adjustable and shall hold the medical respirator firmly and in comfortable position so that it can meet the requirement specified in the standard.

5 PERFORMANCE REQUIREMENTS

5.1 The medical respirators shall conform to the requirements as specified in Table 1. Medical respirators have been categorized into two classes based on performance IN95 and IN99.

Table 1 Performance Requirements for Medical Respirator
(*Clause* 5.1)

Sl No.	Characteristic	Requirements		Method of Test, Ref to
		IN95	IN99	
(1)	(2)	(3)	(4)	(5)
i)	Breathing resistance Pa, *Max* (Method 1: Static breathing resistance)			IS 17274 (Part 2)
	a) Inhalation (@30 lpm)	70	100	
	b) Inhalation (@95 lpm)	240	300	
	c) Exhalation (@160 lpm)	300	300	
ii)	Splash resistance, mmHg, *Min*	Pass at 120	Pass at 160	Annex B
iii)	Penetration of filter, percent, *Max* Sodium chloride test method (Full exposure particle penetration test)	5	1	IS 17274 (Part 3)
iv)	Inward leakage, percent, *Max* (*see* Note 1)	11	5	IS 17274 (Part 1)
v)	CO_2 content, percent, *Max*	1	1	IS 17274 (Part 9)
vi)	Cleanliness-microbial (CFU/g)	< 30	< 30	ISO 11737 (Part 1)
vi)	Flammability (resistance to flame, single burner, dynamic test) as received, (optional) (*see* Note 2),	Pass	Pass	IS 17274 (Part 10)
vii)	Biocompatibility Evaluation (optional) (*see* Note 2)			
	a) Cytotoxicity	None	None	IS/ISO 10993-5
	b) Irritation and skin sensitization	Non-irritant and non-sensitizer	Non-irritant and non-sensitizer	IS/ISO 10993-10 and ISO 10993-23

NOTES

1 When tested as per IS 17274 Part 1, the medical respirators fitted in accordance with manufacturer's instructions, at least 46 out of 50 individual exercise results (that is, 10 subjects x 5 exercises) for total inward leakage:

a) Shall not be greater than 11 percent for IN95 and 5 percent for IN99.
b) At least 8 out of 10 individual wearer arithmetic mean for total inward leakage shall not be greater than 8 percent for IN95 and 2 percent for IN99.

2 The requirement of biocompatibility evaluation and flammability of raw material shall be confirmed at designed stage. The biocompatibility evaluation and flammability test shall be carried out once for existing raw material and whenever there is a change in the raw material or source of supply for manufacturing the product.

5.2 The informative annex for user of medical respirator has been given in Annex C.

6 MARKING

6.1 Each piece of medical respirator shall be legibly marked with the following information:

a) Name of the product;

b) Manufacturer’s name, initials or trade-mark, if any;

c) Month and year of manufacture or Batch/Lot No;

d) Class of medical respirator;

e) Instruction for use;

f) Disposability instructions — The manufacturer shall provide the instruction to users for safe disposal of the product as per Biomedical Waste Rules 2016 or applicable rules published from time to time;

g) Additional features of flammability (if applicable);

h) The information whether the material of the product is biocompatible that is meets the requirement of the standard for biocompatibility evaluation — cytotoxicity, irritation and skin sensitization (if applicable);

j) Country of origin; and

k) Any other requirement as per Medical Device Rules, 2017 or as required by the law in force or as agreed between buyer and seller.

6.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

7 SAMPLING AND CRITERIA FOR CONFORMITY

7.1 Lot

All the medical respirators of the same class and material, produced under similar conditions of manufacture shall constitute a lot.

7.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

7.1.2 Unless otherwise sampling plan is specified in the contract or order, the number of respirators to be selected from the lot shall depend on the size of the lot and shall be in accordance with col (2), col (3) and col (5) of Table 2.

7.1.3 These respirators shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

7.2 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

7.2.1 All the medical respirators selected as per col (3) of Table 2 shall be examined for manufacture and workmanship (*see* **4**).

7.2.1.1 Any respirator failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements, if the total number of defectives found in the sample is less than or equal to the acceptance number given in col (4) of Table 3. Otherwise, the lot shall be rejected.

7.2.1.2 Out of the sample already found satisfactory according to **7.2.1.1,** a sub-sample as per col (5) of Table 2 shall be taken. This sub-sample shall be further tested for the remaining requirements.

7.2.2 The lot shall be considered as conforming to the requirements of the specification, if the total number is less than or equal to the acceptance number as given in col (6) of Table 2.

Table 2 Number of Medical Respirators to be Selected
(*Clauses* 7.1.2, 7.2.1, 7.2.1.1 and 7.2.2)

Sl No.	**Lot size**	**Sample size for manufacture and workmanship**		**Sample size for the remaining requirements**	
		No. of Respirator to be Selected	Acceptance Number	No. of Respirator to be Selected	Acceptance Number
(1)	(2)	(3)	(4)	(5)	(6)
i)	Up to 280	13	1	8	0
ii)	281 – 500	20	2	8	0
iii)	501 – 1 200	32	3	13	0
iv)	1 201 – 3 200	50	5	13	0
v)	3201 – 10 000	80	7	20	1
vi)	100 001 and above	125	10	20	1

8 PACKING

The medical respirator shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. Details of the packing shall be as agreed to between the buyer and the seller. Packaging of the product shall be such as to maintain the integrity of the product throughout its shelf life.

ANNEX A

(*Clause* 2)

LIST OF REFERRED STANDARDS

IS No.	*Title*
IS 4905 : 2015	Random sampling and randomization procedures (*first revision*)
IS 8347 : 2008	Respiratory protective devices — Definition, classification and nomenclature of components (*first revision*)
IS 9623 : 2008	Selection, use and maintenance of respiratory protective devices — Code of practice (*first revision*)
IS/ISO 10993-5 : 2009	Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity
IS/ISO 10993-10 : 2021	Biological evaluation of medical devices: Part 10 Tests for irritation and skin sensitization
ISO 10993-23 : 2021	Biological evaluation of medical devices — Part 23: Tests for irritation
IS 16546 : 2016/ISO 16603 : 2004	Clothing for protection against contact with blood and body fluids — Determination of the resistance of protective clothing materials to penetration by blood and body fluids — Test method using synthetic blood
IS 17274	Respiratory protective devices — Methods of test and test equipment
(Part 1) : 2019/ISO 16900-1 : 2014	Determination of inward leakage
(Part 3) : 2019/ISO 16900-3 : 2012	Determination of particle filter penetration
(Part 9) : 2019/ISO 16900-9 : 2015	Determination of carbon dioxide content of inhaled gas
(Part 10) : 2019/ISO 16900-10 : 2015	Resistance to ignition, flame, radiant heat and heat
ISO 11737-1 : 2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products

ANNEX B

[*Table* 1, *Sl No.* (ii)]

METHODS FOR DETERMINATION OF SPLASH RESISTANCE

B-1 PRINCIPLE

A volume of synthetic blood is disbursed at a specimen respirator by a pneumatically controlled valve from a set distance at specified pressure to simulate the impact of blood or other body fluid onto the specimen. The velocity and volume of fluid are set to simulate a given health care scenario.

B-2 APPARATUS AND REAGENTS

B-2.1 A suitable test apparatus to dispense a specified volume of synthetic blood through a small diameter canula (l .27 cm long with an internal diameter of 0.084 cm) over a controlled amount of time at a specimen respirator a set distance away. The test apparatus consists of a specimen holding fixture, a targeting plate, a pressurized fluid reservoir, a pneumatically actuated valve with interchangeable canula and a valve controller. The test apparatus includes a base for more convenient mounting of the components and a hood or other components to contain or control the splash.

B-2.2 Synthetic Blood (*see* IS 16546)

B-2.3 Isopropanol, laboratory grade, for cleaning the apparatus.

B-3 TEST SPECIMEN

B-3.1 Use complete medical respirators as the test specimen. If in the design of a medical respirator, different materials or thickness of material are specified at different locations, test each area of the specimen separately. If in the design of a medical respirator, seams are claimed to offer the same protection as the base material, test these areas of the respirator separately.

B-3.2 Prior to test, the specimens shall be conditioned to moisture equilibrium in the standard atmosphere of temperature (27 ± 2) °C and relative humidity of (65 ± 2) percent. When the test specimens have been exposed to standard atmosphere for at least 6 h in such a way to expose as far as possible, all portions of the specimens to the atmosphere, they shall be deemed to have reached moisture equilibrium.

B-4 PROCEDURE

B-4.1 Place a small droplet (approximately 0.1 ml) of the synthetic blood on the normal inside surface of an extra medical respirator. The droplet must remain easily visible to ensure that a droplet penetrating the material shall be seen. If not, use talcum powder on the normal inside surface of the medical respirator to enhance droplet visibility.

B-4.2 Mount a specimen on the specimen holding fixture and position the specimen so that the impact of the synthetic blood occurs in the desired area of the respirator. If the respirator contains pleats, spread the pleats out when mounting the respirator onto the test fixture to present a single layer of material as the target area. Use the centre of the specimen as the target area. The inside of the respirator shall contact the entire perimeter of the viewing hole. The specimen respirator shall be supported by the specimen holding form. Re-mount the specimen respirator, if necessary.

B-4.3 Locate the exit of the canula 30.5 cm from the target area of the specimen respirator· Dispense the synthetic blood (approximately 2 ml) at a pressure of 120 mm or 160 mm of Hg (as applicable) onto the specimen medical respirator. Ensure that the synthetic blood hits the target area of the medical respirator.

B-4.4 Inspect the viewing side of the specimen for synthetic blood within 10 s of dispensing the synthetic blood against the target area. Using suitable lighting note whether any synthetic blood, or other evidence of wetness, or both appears on the viewing side of the specimen. Use a cotton absorbent swab or similar item to lightly daub the target area, if doubt exists for visible penetration of the synthetic blood.

B-5 TEST REPORT

Any evidence of synthetic blood penetration on the inner facing of the medical respirator constitutes a failure at the specified pressure.

ANNEX C

(*Clause* 5.2)

INFORMATION FOR USERS

C-1 A medical respirator used in a healthcare setting that is worn by healthcare professionals (HCPs) during procedures to protect both the patient and HCPs from the transfer of microorganisms, body fluids, and particulate material at different penetration levels of IN95 and IN 99.

C-2 The degree of protection offered by a respirator depends on a number of factors such as the penetration of filter media and the fit of the respirator on the wearer's face. Different designs are suited for different applications and the careful choice of respirator is therefore important in order to achieve the desired result.

C-3 The penetration capacity of respirator materials can vary depending on the filter media. The fit of respirators varies considerably from those which are held in place by ear loops fastened behind the wearer's ears to those with tie bands around the head and a nose clamp that can be shaped to the wearer's nose.

C-4 The considerable variations in results when respirators are tested in vivo results in the need for large groups of test subjects and observations. It is thus usual to characterize respirator performance using in vitro tests of the material from which the respirator is made. It is, however, important to consider the fit of the respirator carefully when a respirator for a certain application is chosen. Users should request such information from their suppliers.

C-5 A further factor to be considered is the capacity of the respirator to absorb moisture from the exhaled air and thereby to maintain its performance over a longer period of time. The more advanced designs easily maintain their performance throughout even very long operations whereas the less advanced ones are intended only for short procedures. There is no scientific evidence that demonstrates a limitation in wearing time for the advanced medical respirators.

C-6 The contamination risk resulting from hand contact with a used respirator means that it is essential that the respirator is taken off and disposed of when no longer worn over nose and mouth. When there is a further need for protection then a new respirator should be put on. Touching a used respirator or putting on a new one should always be followed by a full hand disinfection procedure.

C-7 It is important to wear your respirator properly, so it forms a seal to your face. Gaps can let air with respiratory droplets leak in and out around the edges of the respirator. Gaps can be caused by choosing the wrong size or type of respirator or when a respirator is worn with facial hair.

C-8 Do not wear medical respirators,

a) If they have exhalation valves, vents, or other openings;
b) If it is hard to breathe while wearing them;
c) If they are wet or dirty; and
d) With other masks or respirators.

C-9 Medical respirators are typically designed to be used for the use of adults and therefore they have not been tested for broad use in children. So, the usage of medical respirator for children are not recommended by this standard.

C-10 In case of wearer has a hard time breathing, gets dizzy, or has other serious symptoms while you are trying to get the respirator to fit better, choose a surgical face mask or regular cloth mask. They should seek immediate healthcare provider advice and to continue the suitable local government norms to protect themselves and others.

ANNEX D

(*Foreword*)

COMMITTEE COMPOSITION

Technical Textiles for Medtech Applications, TXD 36

Organization	*Representative(s)*
The South India Textile Research Association, Coimbatore	Dr Prakash Vasudevan **(*Chairperson*)**
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